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14. ABSTRACT The National Biocontainment Training Center (NBTC) provideds standards-based theortical and practical training to trainees and professionals preparing for work in biocontainment laboratories where especially dangerous pathogens will be handled. Training s staged and appropriately targeted to requirements for biological safety level 2 (BSL-2), BSL-3 and BSL-4. Structured coursework is designed to prepare trainees to safely manipulate pathogens, including growth, genetic and antigenic characterization, and molecular studies of pathogenesis. Coursework includes both theoretical training and supervised hands-on procedures tailored to meet the specific needs and requirements of the individual trainee.					
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INTRODUCTION

The National Biocontainment Training Center (NBTC) provides standards-based theoretical and practical training to trainees and professionals preparing for work in biocontainment laboratories where especially dangerous pathogens will be handled. Training is staged and appropriately targeted to requirements for biological safety level 2 (BSL-2), BSL-3 and BSL-4. Structured coursework is designed to prepare trainees to safely manipulate pathogens, including growth, genetic and antigenic characterization, and molecular studies of pathogenesis. Coursework includes both theoretical training and supervised hands-on procedures tailored to meet the specific needs and requirements of the individual trainee. Advanced coursework includes hands-on mentored training in the containment laboratories, including consecutively at BSL-3 and BSL-4 levels of containment. Specialized training in the handling of laboratory animals is under development and will be offered during year 2 of activities. Extensive mentored training is offered for scientists at the BSL-4 level through a dedicated fellowship. Fellows work under the close supervision of an established mentor while addressing a research topic of their own choosing. Fellowships are open-ended and fellows progress to full independent access to the BSL-4 laboratory only when the mentor and laboratory director are fully confident of the individual's skills and ability to work independently in this environment. The NBTC also offers a unique training opportunity for building engineers interested in pursuing a career as a biocontainment building engineer. To the best of our knowledge, this is the only such training program in the world. This program is designed as a series of modules which address specific aspects of the construction, maintenance and safe operations of a biocontainment laboratory. The course is tailored to the specific needs of the individual trainee and involves both didactic training and mentored hands-on work using the Galveston National Laboratory (GNL) as its classroom. Over the course of the training period, which is anticipated to require up to two years for completion, the fellow will be directly involved in the maintenance of the laboratory, decontamination of specific laboratories, monitoring and replacement of filters, and a wealth of other duties routinely seen in the operations of typical biocontainment facilities.

BODY

TATRC support for the NBTC formally began on 22 May 2009 and we are now submitting our first annual report for this initiative. The Training Center had been established and operational prior to receiving TATRC funding; consequently, the course structure and procedures were already in place and allowed the Center to implement enhanced training operations almost immediately. From inception to date, the Center has provided training to approximately 1640 participants through the various courses offered. Below we have summarized progress made since receiving TATRC support; funding and accomplishments are organized by each specific aim as they were presented in our original proposal.

Staffing Report

The NBTC relies on a cadre of highly skilled scientists, engineers and technicians to offer a robust portfolio of training opportunities to trainees and professionals working in the field of biocontainment. A summary of these individuals and their roles in the operation and management of the NBTC is below.

Dr Tom Ksiazek. Leadership of the overall NBTC program is provided by Dr Tom Ksiazek, a veteran of nearly four decades of research and development addressing some of the most dangerous pathogens known to humankind, including the filoviruses, Ebola and Marburg, as well as other causes of viral hemorrhagic fevers such as Crimean-Congo hemorrhagic fever, yellow fever and dengue. Dr Ksiazek also oversees the BSL-4 mentored fellowship program and is responsible for the selection of fellows and for monitoring their progress. As the director of the GNL BSL-4 laboratories, he has ultimate responsibility for the individuals working in this space and as such has final approval in determining when an individual has successfully mastered the essential skills needed to safely work independently in the BSL-4 environment.

Dr Anne-Sophie Brocard. Classroom and laboratory training is directed by Dr Anne-Sophie Brocard, an accomplished virologist and experienced trainer who has directed the training center since its inception. Dr Brocard provides both theoretical and practical training to trainees, and monitors their progress as they develop appropriate skills for work at each level of biocontainment.

Ms Je T'aime Newton. Dr Brocard is ably assisted by Ms Je T'aime Newton, a highly experienced instructor with extensive expertise. Ms Newton provides specialized training at all levels of containment, but is responsible for preparing trainees for BSL-4 investigations, focusing her efforts on the proper care, use and maintenance of the protective "space suits" used in the BSL-4 laboratory, and other aspects of work in this highly specialized environment.

Ms Vicki Jones. Ms Jones is a critical member of the teaching faculty who assists as a trainer in both the theoretical and practical training modules.

Ms. Belinda Rivera and Mr. Jason Hardcastle recently joined our team as animal and in-vitro trainers.

Ms Dee Zimmerman is the director of the University biosafety program and offers guidance in the regulatory requirements for operation of any biocontainment facility.

Ms Paige Carness. A dedicated module on biosecurity is included in the portfolio of training opportunities and the content of this course is the responsibility of Ms Carness.

Mr Lee Thompson and Mr Miguel Grimaldo. The building engineering fellowship is coordinated through the efforts of Mr Lee Thompson and Mr Miguel Grimaldo (not currently funded by this award). They are responsible for the content development of each module of the building engineering fellowship and they also provide the dedicated instruction associated with each module. They serve as the primary mentors for the building engineering fellows.

Ms Bonnie Walters was employed as a business manager for the NBTC during a portion of the year just completed, but she resigned for personal reasons. Recruitment of a replacement is underway and we anticipate filling this vacancy in the next 60 days.

Dr Gavin Bowick was a senior biocontainment fellow preparing for work in the BSL-4 laboratory for much of the year just completed. Dr Bowick is a virologist working on

arenaviruses, the cause of viral hemorrhagic fevers. Dr Bowick's training was interrupted due to visa issues and he has returned to his home in the UK while this is being resolved. We anticipate that he will return in the coming months and will complete his fellowship training. He is also a candidate for a permanent position on the UTMB faculty.

Dr Janice Endsley is an assistant professor on the faculty of UTMB and entered the BSL-4 fellowship program in 2010. Dr Endsley is an expert in tuberculosis and is preparing for work with XDR-TB. We anticipate that Dr Endsley will continue in the fellowship for much of the coming year as she gains critical experience and masters skills needed to work in this environment.

Ms Joan Geisbert will join the NBTC in July 2010 to assist in training at the BSL-4 level. Ms Geisbert has over 30 years experience in BSL-4 laboratories and has worked extensively with experimentally infected animals, including non-human primates, under containment conditions. As our animal handling in containment training module is developed, Ms Geisbert will play a key role in leading this effort.

Additional Mentors. We anticipate expanding our cadre of skilled mentors to provide oversight and supervision of trainees as they complete their hands-on training under BSL-3 or BSL-4 laboratory conditions. Mentors will be existing faculty members who have earned independent access to the containment laboratories, and they will incorporate this added duty into their existing activities.

Dr James Le Duc. Dr Le Duc serves as the principal investigator for the NBTC award and is responsible for programmatic oversight, budgetary issues and reporting requirements. Dr Le Duc has nearly four decades of experience in the conduct and supervision of research and development activities under biocontainment conditions, and has been intimately involved in the development of national policy in the fields of emerging infectious diseases, bioterrorism preparedness and biocontainment.

To meet the growing demand for training opportunities offered through the NBTC, we are in the process of recruiting additional trainers and mentors. We are also in the process of developing skilled trainers to assist in the education of trainees and fellows in the safe and appropriate handling of laboratory animals in the context of research under biocontainment conditions.

Renovation of Teaching Laboratory facilities.

The teaching laboratory is a critical asset of the NBTC designed to offer trainees a realistic exposure to the conditions and equipment they will typically encounter as they conduct their studies in the containment laboratory. At the BSL-2 level, this typically includes a biological safety cabinet where most handling of pathogens takes place. It also includes limited specialized equipment, as well as facilities to manage laboratory waste and storage of pathogens. Training for individuals preparing for work in the BSL-3 laboratory includes a dedicated area where individuals master the donning and doffing of protective gear and its proper disposal. Those going on to prepare for work in the BSL-4 laboratory have specialized training in the care and use of the "space suit" that is routinely worn there. This includes inspection of the suit for any evidence of leaks prior to use, gaining experience and familiarity in the wearing of the suit, use of compressed air hoses, and training in emergency procedures. In order to provide this training under

realistic conditions, the training facility has been outfitted with a breathing air compressor and a mock laboratory where trainees can experience wearing the suit and become familiar with working in this unique environment. Some people discover that they experience claustrophobic reactions when wearing a suit, and this practical, realistic suit training environment allows them to overcome any such reactions under well-controlled conditions, or decide that this work is not a good fit for them.

A key benefit of the support provided to the NBTC is the availability of resources that allowed for the renovation of our existing teaching laboratory facilities. This work has been in progress throughout this funding period and is now complete. We have completely refurbished the training facility to significantly expand the mock laboratory space available to us, and to enhance the breathing air compressor and suit training area. There have been several complications as this work has progressed, but the work is now completed and the mock training laboratory is now in full use. We have used existing/interim BSL-2 laboratory space in the GNL for training throughout the year, so there has been no significant delay in the advancement of our trainees as these renovations were being made. Similarly, we used the west end BSL-4 laboratory in the GNL for training at this level of containment.

Laboratory training is conducted in a mock training laboratory with authentic laboratory equipment utilizing non-infectious materials. Entry into the lab is through a double door anteroom with directional airflow and mock pressure monitors. The laboratory has three class II biological safety cabinets, two of which are constructed with see through panels which allow the trainer to introduce smoke into the BSC to visualize air movement within BSC. There is a third BSC class II cabinet on order which will have see through panels and BSL-4 air connections ports. Two of the BSC will be equipped with a camera inside that will allow us to perform remote demonstrations. The laboratory will also have two cameras installed for remote demonstrations. The laboratory will have two class III glove boxes, incubators, centrifuges, bench top autoclave, refrigerator, -80 freezer, dunk tank, general laboratory equipment to allow for BSL-2 to mock BSL-3 and -4 laboratory work. The laboratory is equipped with a compressor and air lines for practice in the suit check examination and use of BSL-4 suits within that facility prior to the trainee entering the active BSL-4 laboratories. The laboratory has airline drops allowing the trainee to work throughout the laboratory with the ability to connect and disconnect airlines as needed.

Overview of NBTC Training

The NBTC provides a series of training modules involving a mixture of didactic instruction and hands-on training to be carried out within an existing mock BSL-3/-4 training laboratory located within the Environmental Health and Safety Office space in the Materials Management Building on the UTMB campus. The intent of the NBTC is to promote good techniques and safe procedures to be used at all biosafety levels, and to provide consistency in research practices. The program ensures that all training attendees have the same general biosafety training at BSL-2 and -3, and if necessary BSL-4, prior to entering a biocontainment laboratory, thus ensuring that safety standards are observed and good practice is pursued.

BSL-2 and BSL-3 Training

The BSL-2 and -3 training provide a multi-phased approach:

- the assessment phase
- the training phase
 - theory
 - hands- on practicum
- final assessment

Each person begins with an assessment that includes a written test focusing on safety related topics, hands-on skills related to protocols based on their research using appropriate biosafety practices and procedures. During the assessment the trainer does not intervene and notes both safety and scientific techniques employed. This allows the determination of experience and level of training that will be required for each trainee. Once the assessment is completed the results are reviewed with the trainee and the specific areas of training focus are identified. A written report is sent to the trainee and their principal investigator or supervisor.

The training phase includes a theoretical class which covers the following topics:

- Biological safety levels 1 through 4, standard microbiological practices, special practices, safety equipment and laboratory facilities.
- Personal protective equipment, types of respiratory protection, gloves, gowns, use and disposal.
- Proper use of the biological safety cabinet (BSC), how the cabinet functions, monitoring the BSC functions, setting up the work field, decontamination prior to and after work, and spill response in the BSC.
- Procedures with the potential for creating infectious aerosols, how to recognize aerosol producing devices and how to mitigate and control aerosol production.
- Emergency procedures, spills in the laboratory, BSC, centrifuge, incident response, first aid, reporting procedures, and medical emergencies in the lab.
- Waste management, types of disinfectants, types of waste generated, the differences in disinfection, decontamination and sterilization.
- Introduction to select agent rules and NIH-OBA guidelines.

The hands-on practicum compliments and reinforces the theoretical class and allows the trainee to experience different scenarios in a non-hazardous environment. It allows the trainer to observe, advise, and correct the trainee's techniques in the laboratory relative to safety as well as scientific issues (e.g. contamination of cultures). The practicum is specific to biosafety and agents to be used (e.g. bacteria, parasites, viruses). This approach also allows the use of specific protocols or facility specific practices the trainee brings with them. Emergency response and spill training allows the trainee to visualize and respond to spills and contamination with the use of florescent dye and breakable training lab ware.

The final assessment is identical to the initial assessment, with a written exam and hands on skills assessment. Once the trainee has completed and passed the final

assessment the trainee is provided with a certificate of training for the biosafety level they completed. A report is sent to the principal investigator, trainee and laboratory director.

Animal BSL-3 Training

An animal biosafety training program was developed on the same concepts as the BSL-3 program. Trainees must have completed the BSL-3 training before commencing ABSL-3 training.

The training phase includes a theoretical class which covers the following topics:

- Personal protective equipment, types of respiratory protection, gloves, gowns, use and disposal.
- Proper use of the biological safety cabinet (BSC), how the cabinet functions, monitoring the BSC functions, setting up the work field, decontamination prior to and after work and spill response in the BSC.
- Procedures with the potential to create infectious aerosols, how to recognize aerosol producing devices and procedures and how to mitigate and control aerosol production.
- Emergency procedures, spills in the laboratory or in the BSC, incident response, first aid, reporting procedures, and medical emergencies in the lab.
- Waste management, types of disinfectants, types of waste generated, the differences in disinfection, decontamination and sterilization.
- The hands-on practicum compliments and reinforces the theoretical class and allows the trainee to experience different scenarios in a safe environment. It allows the trainer to observe, advise, and correct the trainee's techniques in the laboratory relative to safety as well as animal handling. The practicum is specific to biosafety and animal species to be handled. This approach to training also allows the use of specific protocols or facility specific practices the trainee brings with them.

In the third phase, the final assessment includes a written exam and a hands-on skills assessment. Once the trainee has completed and passed the final assessment the trainee is provided with a certificate of training for the biosafety level they completed.

BSL-4 Training

BSL-4 training rests upon a firm adherence to the principles and specific practices of safe BSL-3 research. This prevents an over-reliance on the BSL-4 suit as a primary means of containment, and makes the suit environment an operationally redundant means of protection, significantly enhancing protection. Accordingly, individuals who are selected for BSL-4 training will have completed training at BSL-3 and have been approved for independent access to the BSL-3 laboratories. These individuals would then complete the BSL-4 modular training.

Specific Aims

Aim 1: To provide standards-based, high containment laboratory safety knowledge.

Standard training activities for UTMB staff, trainees and investigators from outside the University have been in place throughout the year. The number of individuals trained at each level is summarized in Table 1 below and the associated figures. As summarized above, the topics typically covered in this introductory training include the principles of basic safety precautions in the laboratory, routine rules and regulations designed to protect the individual and environment from accidental contamination by an infectious microbe, and the care and use of the biological safety cabinet. Also covered are the appropriate procedures of clean-up following a spill, decontamination procedures, principles of the care and use of autoclaves and other essential equipment. A summary of the modules covered in this course is included in Appendix 1.

Aim 2: To provide standards-based, high containment laboratory hands-on training.

Training offered under this Aim is directed at providing trainees with practical, real-world training in the laboratory setting. Course content is tailored to include those procedures and the use of specific equipment likely to be encountered by the trainee in their routine work. Thus, those destined to work in a virology laboratory may focus on those protocols most appropriate for use in a virology laboratory as opposed to those typically used when working with bacteria. There are, of course, common practices used in any BSL-2 laboratory and training on the safe conduct of these procedures is the foundation of this course. Training typically is undertaken in small groups of only one or two individuals, allowing for intense interaction between the instructor and trainees. By actually doing the procedures essential to their day-to-day laboratory work under the close supervision an instructor (with the use of indicator dyes that allow clear recognition of contamination), the trainee quickly grasps the key teaching points and rapidly masters safe laboratory practices. Training is offered in the newly renovated training laboratory described above.

The numbers of individuals trained under Aim 2 for the NBTC are summarized in Table 1 below and include a total of 91 individuals who have complimented their theoretical training at the BSL-2 level with practical hands-on BSL-2 training in the laboratory setting. A total of 80 were trained at the high containment BSL-3 level with practical hands-on experiences. Animal BSL-3 (ABSL-3) theoretical training was provided to 53 individuals, and 36 completed their hands-on training. Sixteen individuals participated in maximum containment BSL-4 training.

Aim 3: To provide topic-specific training.

Autoclave Operations. A routine requirement for all persons working in the containment laboratories is the need to be able to properly operate the autoclaves. A dedicated training session is offered to all individuals as a separate element of their orientation to the GNL, and this training is offered to individuals working in other laboratories using the same or similar equipment. During the first year of support we trained 195 individuals in the proper care, use and operations of autoclaves. As several new hiring actions within the GNL occur routinely, we anticipate ongoing demand for this training through coming years.

Aerobiology. The GNL contains aerobiology laboratories at both the BSL-3 and BSL-4 levels of containment. The BSL-3 facilities were fully commissioned and approved for use by the CDC and USDA during the year just completed; however, the BSL-4 facilities were only finally approved for full operations very recently. These facilities are highly complex and require specialized training not only in the operation of this sophisticated equipment, but also in the proper care and handling of the laboratory animals that will be experimentally exposed. During the course of the year we have trained 19 individuals for work in the BSL-3 facility, and during the coming year we anticipate that many of these same persons will acquire training in the BSL-4 facility as well.

External Training: A local institution requested that we provide BSL-3 training for their staff prior to opening their new BSL-3 facility. Therefore 26 trainees received theoretical BSL-3 training of which 9 trainees also received hands-on training. As part of their training process we will be also providing ABSL-3 training to their scientist and support staff.

Gamma Irradiator Training. BSL-4 laboratories utilize a number of techniques to inactivate biological materials prior to removal from the containment laboratory. One of the most frequently utilized means of removing materials from the BSL-4 laboratory is inactivation by gamma irradiation. In an effort to update training of individuals that use gamma irradiation at UTMB, a new training module was formulated to provide background radiation biology information, radiological and biological safety training, select agent and radiological security training, introductory training on dosage determination and method validation, and practical instruction on the use of the devices used for gamma bombardment. Instructors included members of the Radiation Safety Office and Biological Safety Office of UTMB's Environmental Health and Safety Office and Faculty and Staff from the Galveston National Lab/Keiller Complex. Nineteen individuals were trained in the session offered on 25 May 2010. Materials developed for the course have been organized and will form the basis for future training and refresher courses at UTMB and for others interested in the subject matter.

High Through-put Screening. We continue to work to develop a systematic training program focused on the safety concerns associated with high through-put screening. Four of the original 8 trainees introduced to the program are continuing personalized training on this unique equipment, and we anticipate an additional 2 trainees to start during the next quarter. In addition, we purchased a major piece of equipment, a pyrosequencer, to augment the existing robotics and PCR equipment already in use in the laboratory. All this equipment was used to assist the Texas Department of State Health Services and other collaborating laboratories in response to the emergence of Influenza A H1N1 that recently occurred. We will continue to develop this capability in future years as it represents the cutting-edge interface between technology and biological sciences and as such potentially creates new challenges for biological safety.

Aim 4: To provide a mentorship program for scientists working in BSL-3/ABLS-3 or BSL4/ABSL4 facilities.

A total of 53 trainees and staff were enrolled in ongoing mentored guidance in the BSL-3 laboratory suites during the year just completed, while 16 participated in supervised training at the BSL-4 level. Mentored training typically extends beyond a

given reporting quarter. A more extensive listing of the number of individuals trained during the year can be found in Table 1 below.

Aim 5: To establish a fellowship program for scientists and building engineers working in BSL-3/ABSL-3 or BSL-4/ABSL-4 facilities.

The high and maximum containment fellowship program for scientists is in place and we have two fellows now in training. Gavin Bowick, PhD, is currently enrolled in the mentored training phase of BSL-3, and will soon begin his mentorship in the BSL-4 laboratory. Dr Bowick is a junior faculty member at UTMB and is studying the pathogenesis of Junin virus, an arenavirus endemic in Argentina and a Category A recognized bioterrorism threat agent. Junin virus is a Select Agent. As indicated above, Dr Bowick's training was interrupted due to visa issues and he has returned to his home in the UK while this is being resolved. We anticipate that he will return in the coming months and will complete his fellowship training. He is also a candidate for a permanent position on the UTMB faculty. Dr Janice J Endsley, has now begun as the second fellow sponsored by the program. As indicated above, Dr Endsley is an expert in tuberculosis and is preparing for work with XDR-TB. We anticipate that Dr Endsley will continue in the fellowship for much of the coming year as she gains critical experience and masters skills needed to work in this environment. As the GNL BSL-4 laboratories become operational in the next few months, we anticipate the possibility of expanding the number of fellows.

The containment laboratory building engineer fellowship is unique and is, to the best of our knowledge the only one of its kind. It promises to set a new standard for preparation of individuals working in this highly specialized environment. Unlike the fellowship for scientists, where the candidate is likely to already have solid technical skills and will be applying them in the containment environment, we anticipate that entering building engineers will require a more structured course of study. Consequently, we have identified 14 distinct modules to be covered during the course of the 2 year fellowship (see Appendix 1). These modules will cover basic microbiology, provide an overview of biosafety and biocontainment principles, construction methodologies specific for each level of containment, risk assessments, select agent regulations, formal Good Laboratory Practices, annual certification of laboratories, testing of HEPA filter housing and filters, air balancing procedures, building automated systems and engineering controls, effluent treatment systems, autoclaves care and use, decontamination procedures, biosafety cabinet certification, and laboratory operations SOP development and record keeping. During the course of their training, we anticipate that fellows will directly participate in each of these activities, as well as be personally involved in the planned shut down and decontamination of containment suites, validate decontamination, and conduct and oversee maintenance activities. Plans are being developed to allow fellows to visit other high and maximum containment laboratories across the nation during the second year of their fellowship to better understand the diversity of facilities and variations in containment practices.

At the current time, our first biocontainment engineering fellow is in-processing and we anticipate that he will begin formal training within the next 60 days. This individual comes from the construction industry and was directly involved in the construction of the GNL, so he is especially well qualified to participate in the

fellowship. We are designing his course of study to be flexible to allow him to participate in the fellowship while retaining some of his duties with his current employer.

This past year we also assisted the University of Texas El Paso (UTEP) safety and facilities staff by hosting a visit to the GNL to provide them a better understanding of issues related to BSL-3 laboratory facilities operations. The topics discussed included Biocontainment Operations, BSL-3 facility maintenance, the Select Agent registration process, record keeping, the benefits for annual biocontainment maintenance shutdowns, and an extensive tour of BSL-3 laboratories and support spaces.

UTEP participants:

Greg McNicol – Associate Vice President for Business Affairs

Robert Moss – Assistant Vice President for Environmental Health & Safety

Emilio Rodriguez – Environmental Health & Safety

Danny Cisneros – Facility Services

Aim 6: To provide training in Biosurety and Biosecurity for both leaders of biocontainment laboratories and for staff working in such facilities.

Over the first year of support we have actively participated in the national dialogue over the critical elements necessary for an effective program in biosurety and biosecurity of biocontainment laboratories. This remains an evolving field, with guidelines still being developed and a legal foundation yet to be established. As these issues are being debated nationally, we have continued to provide our expert opinion through the American Society of Microbiology and other organizations at the fore of these discussions. We have also participated in ongoing discussions on these topics hosted by the National Science Advisory Board for Biosecurity (NSABB) and the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight. Biosurety and biosecurity are currently covered in our theoretical training sessions, and we are in the process of developing a structured course to more specifically address biosurety and biosecurity in depth. We anticipate posting this course on our internal website as an educational tool to augment our more formal training opportunities and to complement lectures already offered. Depending upon the success of this internal posting, we will then consider posting the course on our general website where it would be available to the general public.

Table 1. Summary of training courses offered and number of participants in each course, May 2009 through March 2010.

Module	May- Sept 2009	Oct-Dec 2009	Jan-March 2010	April- June 2010	Total
BSL-4	4	5	2	5	16
BSL3	26	19	14	21	80
BSL2 Theoretical	71	36	30	62	199
BSL2	42	22	11	16	91
ABSL3	19	10	8	16	53
Theoretical					
ABSL3 hands on	24	5	7	6	42
Graduate Program	14	34	0	0	48
Aerobiology	19	0	0	0	19
Autoclave	135	13+(47 refresher)	0	0	195
High Through-put Safety training	NA	8	0	0	8
Theoretical non human primate	16	0	0	0	16
BSL3 mentorship	26	10	0	17	53
Specialized training (Assay Development division) BSL3 theoretical	0	18	0	17	35
Total trained	396	227	72	160	855

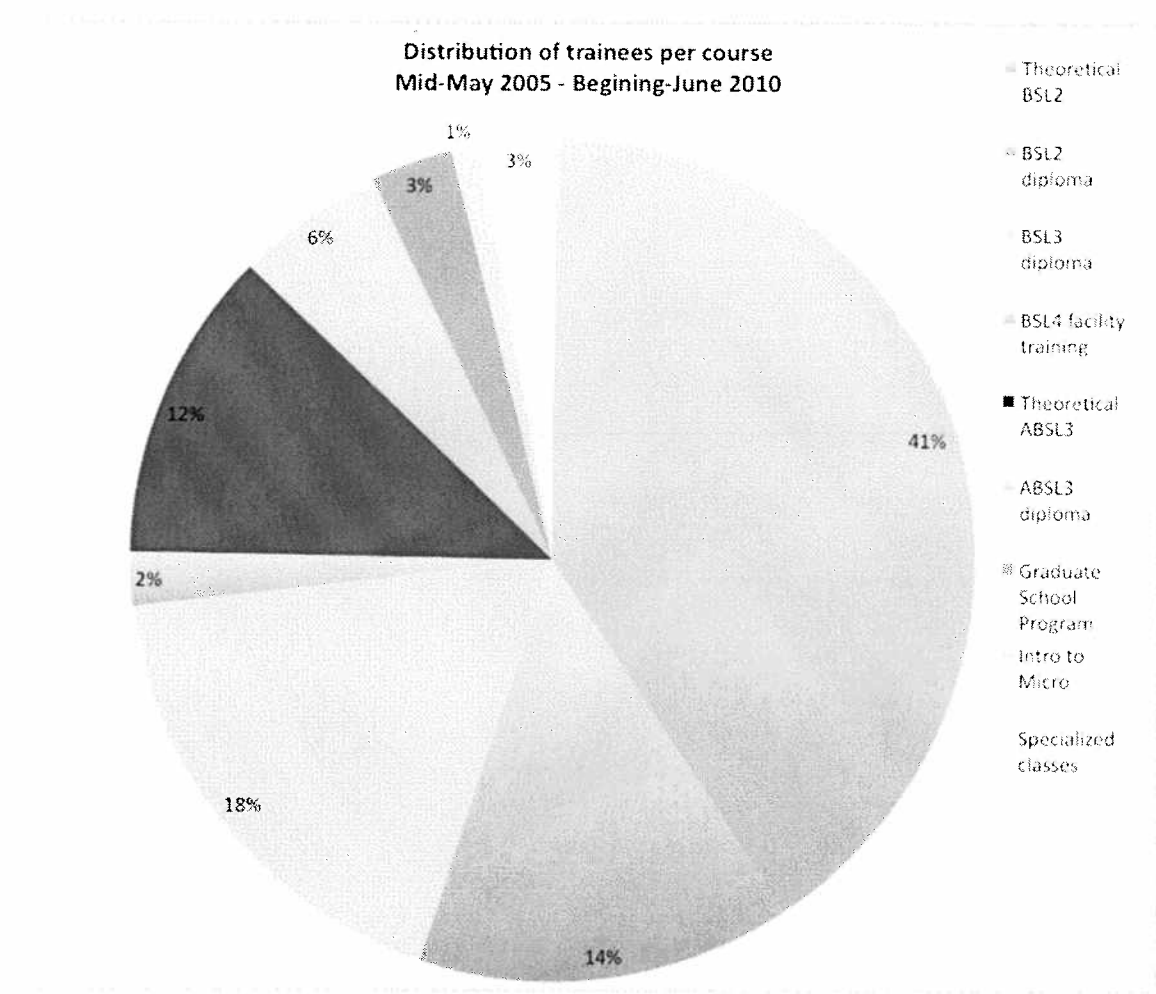


Figure 1: Distribution of trainees based on the courses taken over the past five years. Specialized classes include number of trainees that have only taken theoretical training on BSC and BSL-3 theoretical. As expected the number of trainees follows the normal biosafety level pyramid with a large amount of BSL-2 trainees and then fewer as the biosafety level increases.

Distribution of trainees by job discription
May 2005-June 2010

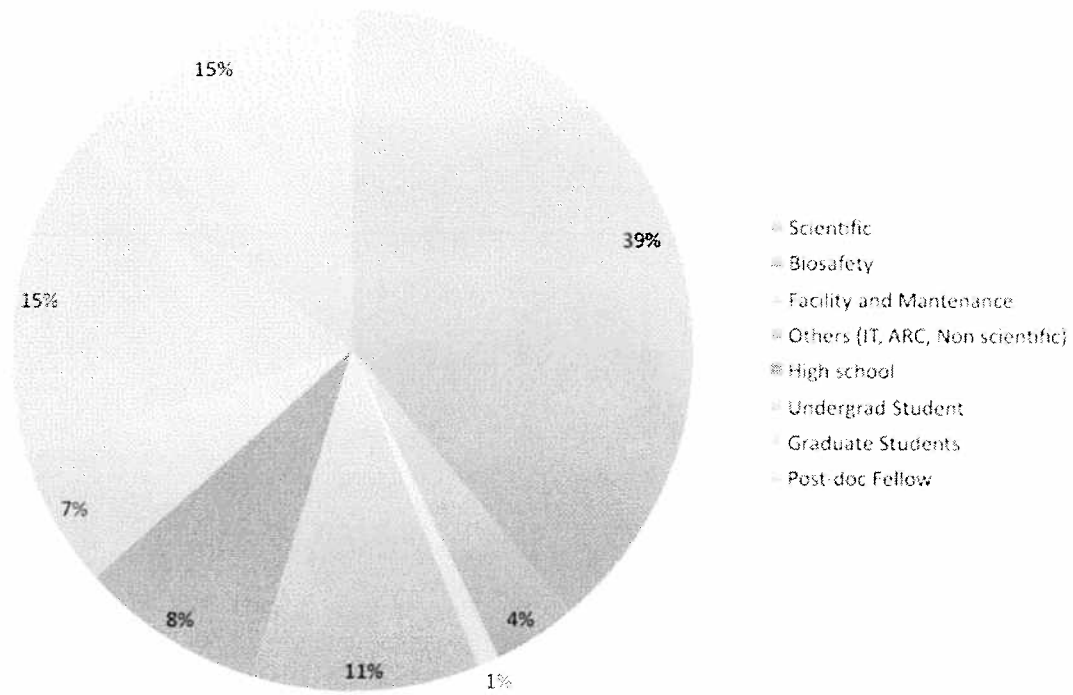


Figure 2: Distribution of trainees based on their main job occupation. Others include information services personnel, animal care staff, public relations personnel, and lawyers. In this graph we can see that as expected the scientific community is the major beneficiary of the training program, as this was designed specifically for them.

**Distribution of trainees by geographic location
May 2005-June 2010**

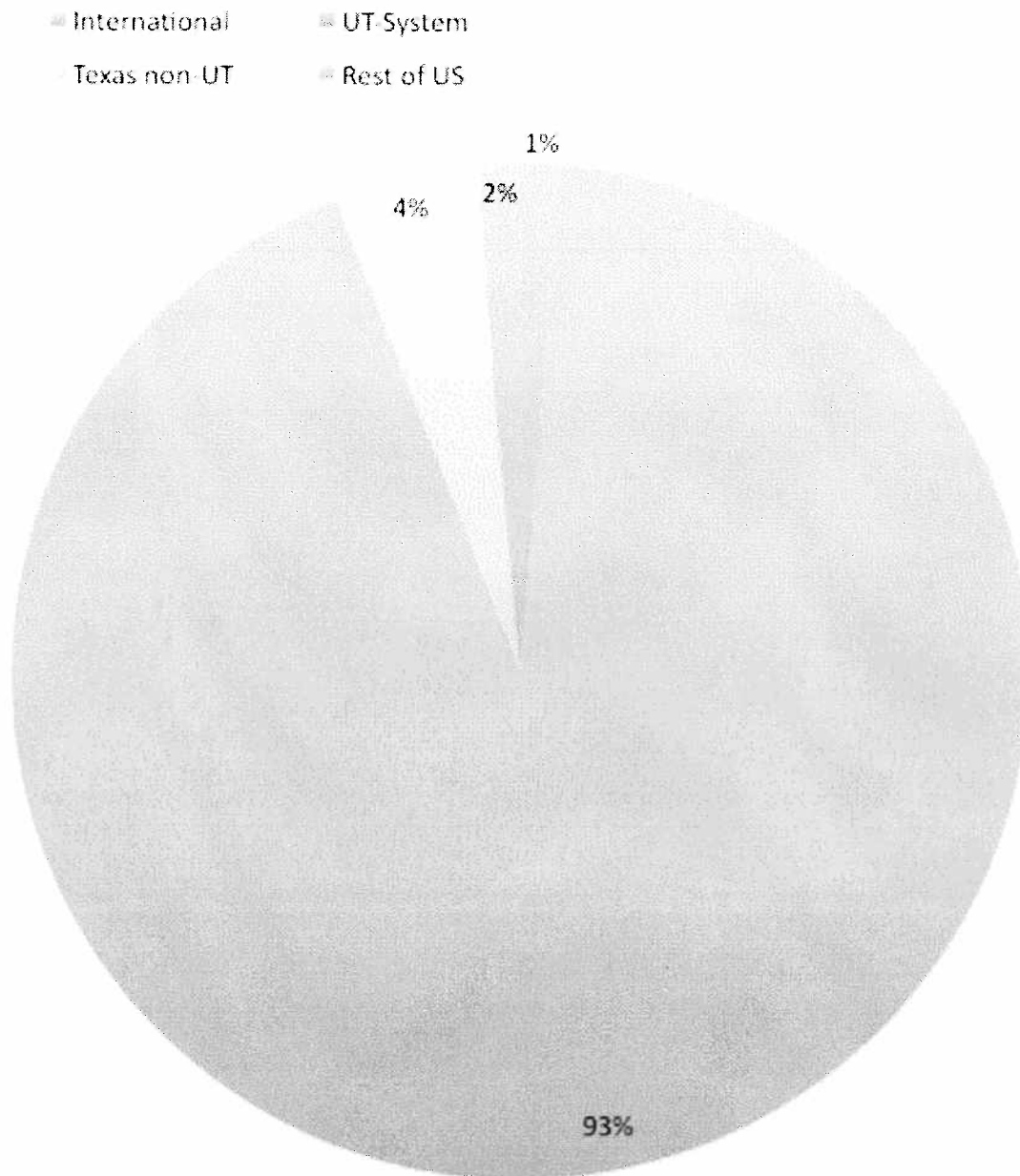


Figure 3: Distribution of the trainees based on their geographic location. UT-System includes all university members of the University of Texas group, of which UTMB is a member.

KEY RESEARCH ACCOMPLISHMENTS

- A comprehensive, standards-based training program has been established and implemented to prepare individuals for work at all levels of biocontainment.
- A fully renovated teaching laboratory allows for full hands-on training under close supervision under realistic containment conditions.
- Advanced, mentored training is available to select fellows with exceptional skill who desire to expand their research activities to include studies at the BSL-4 level.
- A unique fellowship has been created to train the next generation of containment laboratory building engineers prepared to oversee the safe operations of these complex facilities.
- A novel training opportunity addresses the safety considerations emerging at the interface of high through-put screening of potentially infectious material.

REPORTABLE OUTCOMES

- A total of 855 training experiences were provided to trainees, staff and external participants. These courses ranged from basic introduction to biocontainment to mentored hands-on research under BSL-4 containment conditions.
- Two doctoral level fellows are participating in advanced mentored training to become independent investigators able conduct their research under BSL-4 containment.
- One building engineer has been selected and will begin training very soon in the operation and maintenance of a major biocontainment facility.
- Specialized training and a dedicated course (Pre-conference course: "BSL-3 Operations and Management") was provided to participants at an important national scientific meeting relevant to scientists working in biocontainment, the American Biological Safety Association annual meeting (18-21 October 2009). This training was augmented by the availability of literature describing the NBTC program at a manned booth hosted during the meeting as well as at the American Society of Tropical Medicine and Hygiene annual meeting (18-22 November 2009).
- Round table discussions led on the topic of "Training and Mentorship" in biosafety, and two formal presentations, "Creating a culture of Biosafety" and "BSL4 Graduate Student Training Process" were offered at the NBL-RBL facilities network meeting, Boston, 2-5 May 2010.
- Assistance was provided to the University of Texas El Paso in the operation and maintenance of BSL-3 containment laboratories.
- A formal report relevant to the safe operations of containment laboratories was published in the peer reviewed journal, *Emerging Infectious Diseases*: **Le Duc, J.W.**, Anderson, K., Bloom, M.E., Carrion Jr., R., Feldmann, H., Fitch, J.P., Geisbert, T.W., Geisbert, J.B., Holbrook, M.R., Jahrling, P.B., Ksiazek, T.G., Patterson, J., Rollin, P.E. 2009. Potential Impact of a Two-Person Security Rule on Biological Safety Level-4. *Emerging Infectious Diseases* 15 (7), July 2009 online only. ISSN: 1080-6059.

CONCLUSIONS

The National Biocontainment Training Center offers a robust and intensive training program devoted to all aspects of biological safety, biocontainment, and biosecurity. This program offers unique, hands-on training to trainees, staff and external partners at all levels of biocontainment, including focused, mentored training in the BSL-4 laboratory. Over 850 persons benefited from one or more of these training courses, many of whom are trainees now pursuing graduate education and using these specialized skills in the newly constructed GNL containment facilities. Intensive, mentored fellowship programs were established to offer opportunities for in-depth training in research under BSL-4 conditions and also in containment laboratory operations and maintenance. These fellowships help address the critical national shortage of well-trained containment laboratory scientists and building engineers.

REFERENCES

none

APPENDICES

1. Biocontainment Operations Fellowship Training Modules. Modules vary in length of time and are informally schedule throughout the fellowship to meet the needs of the fellows and staff.

1. Basic Microbiology
2. Overview of Biosafety and Biocontainment Principals
 - a. Microbiological Practices
 - b. Primary containment devices
 - c. Biosafety cabinets
3. Construction Methodologies for BSL3, BSL3E and BSL4 Laboratories
 - a. Architectural details
 - b. Mechanical
 - c. Electrical
 - d. Plumbing
4. Risk Assessments
5. Select Agent Regulations and GLP
6. Annual Certification of Laboratories
 - a. Aerobiology Labs
 - b. BSL3
 - c. BSL4
7. Testing of HEPA Filter Housing and Filters for ventilation Systems
8. Air Balancing Procedures
9. Engineering Controls - BAS
10. Effluent Treatment Systems
 - a. Types
 - b. Validation and Testing
11. Autoclaves
 - a. Cycles
 - b. Validation
 - c. Testing
12. Decontamination
 - a. Types
 - b. Methods
 - c. Validation
13. Biosafety Cabinet Certification
14. Laboratory Operations SOP Developments and Record Keeping.

2. Modules covered under BSL4 training.

- Confirmation that trainee has completed required BSL-3 training requirements and started FBI clearance
- Practical suit training; have trainee put on suit and practice connecting to breathing air
- Confirmation that the trainee has read Biosafety Manual and SOP manual (sign off)
- Explanation of criteria for independent access to the BSL-4 laboratory, including the number of hours of training and approval of mentor and laboratory director
- Walk-thru of outside corridor and familiarization with the 3 levels
- Introduction to and performance of exterior check-off
- Familiarization with chain of command and reporting issues
- General laboratory walk-thru with questions and problem solving session
- Oral explanation of entrance/exit procedures
- Introduction to the suit room with explanation and performance of a suit inspection
- Trainee independently conducts suit inspection
- Explanation of chemical shower procedures and how to properly remove the suit
- Enter laboratory, practice maneuvering and chemical shower exit
- Explanation of shower out and change room policies and procedures
- Explanation of breathing air and back-up breathing air systems
- Overview of chemical disinfectant shower
- Explanation of alarms and response procedures
- Explanation of emergency procedures